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Substitute for form 1449-A (PTO)

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	3
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**Complete if Known**

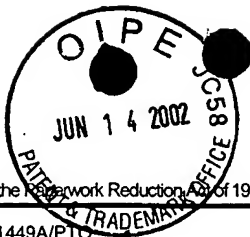
Application Number	10/061,036
Filing Date	January 30, 2002
First Named Inventor	Lloyd G. Simonson et al
Group Art Unit	<del>4743</del> 1645
Examiner Name	(TBA) Su-Ar
Attorney Docket Number	06005.00001

## U.S. PATENT DOCUMENTS

[illegible]

RP Swamy

5-7-03



PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 2 of 3

**Complete if Known**

Application Number	10/061,036
Filing Date	January 30, 2002
First Named Inventor	Simonson et al.
Group Art Unit	4743-1645
Examiner Name	(TBA) SWARTZ
Attorney Docket Number	06005.00001

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

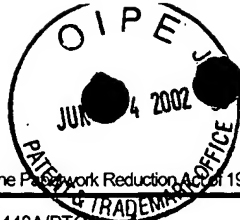
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
MS	✓	Wilkinson R.J., Haslov, K., Rappuoli, R., Giovannoni, F., Narayanan, P.R., Desai, C.R., Vordermeier, H.M., Paulsen, J., Pasvol, G., Ivanyi, J., and Singh, M. Evaluation of the recombinant 38-kilodalton antigen of <i>Mycobacterium tuberculosis</i> as a potential immunodiagnostic reagent. <i>J. Clin. Microbiol.</i> 35(3): 553-7. Mar 1997.	
MS	✓	Maekura, R., Nakagawa, M., Nakamura, Y., Hiraga, T., Yamamura, Y., Ito, M., Ueda, E., Yano, S., He, H., Oka, S., et al. Clinical evaluation of rapid serodiagnosis of pulmonary tuberculosis by ELISA with cord factor (trehalose-6, 6'-dimycolate) as antigen purified from <i>Mycobacterium tuberculosis</i> . <i>Am. Rev. Respir. Dis.</i> 148:997-1001. Oct, 1993.	
MS	✓	Young, D., Kent, L., Rees, A., Lamb, J., and Ivanyi, J. Immunological activity of a 38-kilodalton protein purified from <i>Mycobacterium tuberculosis</i> . <i>Infect. Immun.</i> 54(1): 177-83. Oct, 1986.	
MS	✓	Singh, M., Andersen, A.B., McCarthy, J.E., Rohde, M., Schutte, H., Sanders, E., and Timmis, K.N. The <i>Mycobacterium tuberculosis</i> 38-kDa antigen: overproduction in <i>Escherichia coli</i> , purification and characterization. <i>Gene</i> 117(1): 53-60. Aug. 1992.	
MS	✓	Rosales-Borjas, D.M., Zambrano-Villa, S., Elinos, M., Kasem, H., Osuna, A., Mancilla, R., and Ortiz-Ortiz, L. Rapid screening test for tuberculosis using a 38-kDa antigen from <i>Mycobacterium tuberculosis</i> . <i>J. Clin. Lab. Anal.</i> 12 (2): 126-9. 1998.	
MS	✓	Bassey, E.O.E., Catty, D., Kumararatne, D.S., and Raykundalia, C. Candidate antigens for improved serodiagnosis of tuberculosis. <i>Tubercle Lung Dis.</i> 77:136-145. 1996.	
MS	✓	Kadival, G.V., Chaparas, S.D., and Hussong, D. Characterization of serologic and cell-mediated reactivity of a 38-kDa antigen isolated from <i>Mycobacterium tuberculosis</i> . <i>J. Immunol.</i> 139(7): 2447-51. Oct, 1987. (ABSTRACT ONLY)	
MS	✓	Fujiwara, N., Pan, J., Enomoto, K., Terano, Y., Honda, T., and Yano, I. Production and partial characterization of anti-cord factor (trehalose- 6,6'-dimycolate) IgG antibody in rabbits recognizing mycolic acid subclasses of <i>Mycobacterium tuberculosis</i> or <i>Mycobacterium avium</i> . <i>FEMS Immunol. Med. Microbiol.</i> 24(2): 141-9. Jun, 1999.	

Examiner Signature	B P Swartz	Date Considered	5-7-03
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\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet 3 of 3

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Application Number	10/060,005 101061,226
Filing Date	January 30, 2002
First Named Inventor	Simonson et al.
Group Art Unit	1645
Examiner Name	(FBA) SWARTZ
Attorney Docket Number	06005.00002

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
MS		He, H., Oka, S., Han, Y.K., Yamamura, Y., Kusunose, E., Kusunose, M., and Yano, I. Rapid serodiagnosis of human mycobacteriosis by ELISA using cord factor (trehalose-6, 6'-dimycolate) purified from <i>Mycobacterium tuberculosis</i> as antigen. <i>FEMS Microbiol. Immunol.</i> 3(4): 201-4. Aug, 1991.	
MS		Enomoto, K., Oka, S., Fujiwara, N., Okamoto, T., Okuda, Y., Maekura, R., Kuroki, T., and Yano, I. Rapid serodiagnosis of <i>Mycobacterium avium-intracellulare</i> complex infection by ELISA with cord factor (trehalose 6, 6'-dimycolate), and serotyping using the glycopeptidolipid antigen. <i>Microbiol. Immunol.</i> 42(10): 689-96. 1998.	
MS		Chang, Z., Primm, T.P., Jakana, J., Lee, I.H., Serysheva, I., Chiu, W., Gilbert, F., and Quioco, F.A. <i>Mycobacterium tuberculosis</i> 16-kDa antigen (Hsp 16.3) functions as an oligomeric structure <i>in vitro</i> to suppress thermal aggregation. <i>J. Biol. Chem.</i> 271:7218-7223. 1996.	
MS		Cunningham, A.F., and Spreadbury, C.L. Mycobacterial stationary phase induced by low oxygen tension: cell wall thickening and localization of the 16-kilodalton alpha-crystalline homolog. <i>J. Bacteriol.</i> 180(4): 801-8. Feb, 1998.	

Examiner  
Signature

RPSwartz

Date  
Considered

5-7-03

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